

NOV-29-2005 TUE 12:26 AM BRIAN S STEINBERGER PA

FAX NO. 321 633 9322 11/28/2005

Attorney Dkt: PC-1204

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Charles Crosby
Serial No.: 10/084,008
Filed: 02/27/2002
For: PULSE CAM
Examiner: David M. Shay
Attorney Docket No.: PC-1204

DECLARATION UNDER 37 CFR 1.132

Honorable Commissioner of Patents
and Trademarks
P.O. BOX 1450
Alexandria, Virginia 22313-1450

Sir:

Charles J. Crosby D.O. M.D.(H), FAAOS, FAAO declares that:

1. I am a co-inventor of and familiar with the present U.S. Patent Application 10/084,008 filed 02/27/2002, in the name of the Crosby Advanced Medical Systems, Inc, which is entitled: PULSE CAM.

I am familiar with the Official Action dated August 26, 2005 issued therein and with the prior art references cited in the Official Action, including the Basic TENS CAM DEVICE(also referred to below as TENS CAM Model 100)(Primary Reference). I am also familiar with the patent reference cited in the same Official Action that the Examiner used entitled: MURPHY(Secondary Reference).

2. I received my undergraduate degree as a Bachelor of Science from Springfield College in 1967. I received my advanced degree in D.O(Doctorate of Osteopathy) in 1969 from The Kirksville College of Osteopathic Medicine in 1969.

From 1969 to 1970 I interned at Grandview Hospital, in Dayton, Ohio.

From 1970 to 1971 I interned at Oakwood Hospital in Dearborn, MI.

From 1971-1972 I interned general surgery at Oakwood Hospital in Dearborn, MI.

From 1972-1975 I interned orthopedic surgery at Blodgett Hospital in Grand Rapids, MI.

From 1975-1981 I practiced medicine at Carson City Hospital in Carson City, Michigan.

From 1981-1986 I practiced medicine at Liela Hospital in Battle Creek, Michigan.

From 1987-1989 I practiced medicine at Southside Community Hospital in Farmville, VA.

From 1989-1996 I practiced medicine at Orlando Veterans Administration Clinic, Orlando, FL From 1996-2002 I practiced medicine in private practice in Orlando, FL

My Certifications include:

American Academy of Osteopathic Specialists, Current
Orthopedic Surgery Certification in 1983, 1987

Fellow American Academy Osteopathic Specialists, 1993

Fellow American Academy Osteopathy, 2004

American Osteopathic Association, Current

Neuromuscular Medicine 1997

American Academy of Pain Management, 1999

Board Eligible Clinical Metal Toxicology 2004

Homeopathic Physician, Arizona 2004

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My Teaching Positions have included:

Asst. Clinical Professor Orthopedic Surgery, West Virginia College of Osteopathic Medicine Asst.
Clinical Professor Orthopedic Surgery, Michigan State College of Osteopathic Medicine

I am a member of the following Professional Associations:

American Osteopathic Association

American Academy of Physicians Specialists

American Board of Orthopedic Surgery

Florida Osteopathic Medical Association

American Academy of Osteopathy

The American Osteopathic Academy of Sclerotherapeutic Pain Management

The American Academy of Orthopedic Medicine

The Cranial Academy

American Board of Clinical Metal Toxicology

My current occupation is the Chief Executive Officer(CEO) and the Director of Research, Development and Marketing for Crosby Advanced Medical Systems.

My primary areas of research include medical device development as it relates to the treatment of pain and disease. I have developed and manufactured several products that include the Tens Cam, a single frequency generating crystal that was described in the background section of the subject patent application, the PULSECAM which is described in the subject patent application and the FLASHCAM which is described in a recently filed patent application.

I have authored and co-authored papers in fields on pain and disease management. In addition to this patent application, I have patents pending on a related invention entitled: FLASHCAM.

I have been studying in these areas of pain and disease management using crystal devices for over eight(8) years since 1997. I have also spoken and taught internationally in these areas on numerous occasions and conducted workshops that have taught more than three hundred fifty(350) therapists the treatment processes in these areas.

3. A significant part of the invention is the discovery of a "medical treatment device" having the combination of a "main longitudinal crystal; side crystals arranged about side portions of the main longitudinal crystal...the side crystals being perpendicular to a "longitudinal axes of the main longitudinal crystal, the side crystals being used as antennae to receive ambient energy fields about the device; means for generating a resonating frequency in the main crystal which is focused by the emitting tip portion...toward an effected body part for treatment for up to approximately 2(two) minutes....(with) means for forming a beam from the emitting tip portion having a diameter of approximately 5cm to approximately 6cm", claim 1.

In addition, as significant part of the invention is the novel "method of treating effected body parts" by the combined steps of "providing a main longitudinal crystal....positioning side crystals ...perpendicular to the longitudinal axes of the main longitudinal crystal; picking up ambient energy fields surrounding the tool through the side crystals...emitting pulses having a selected resonating frequency ...toward a body part for treatment... amplifying and diffusing the pulses being emitted from the main body by a lens positioned adjacent to the emitting endrunning the pulse emitting tool up to approximately 2 minutes....", claim 17.

Still furthermore, another significant part of the invention is the combination of a "medical treatment device comprising: a main longitudinal solid crystal....a crystal sphere next to the emitting tip portion of the main longitudinal body....power source for generating a resonating frequency

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in the main crystal through the emitting tip portion of the main longitudinal crystal into an output signal which is amplified and diffused by the crystal sphere toward an effected body part for treatment for up to approximately 2(two) minutes; and side crystals being perpendicular to a longitudinal axes of the main longitudinal crystal, the side crystals being used as antennae to receive ambient energy fields about the device", claim 28.

Specifically, pages 3-10 of the originally filed specification and the other claims specifically refers to these features. These features and their combination are unique and are not anticipated nor rendered obvious from the Primary Reference by itself, or by the Primary Reference in combination with the Secondary Reference listed above.

As previously noted I am a Board Certified Orthopedic Surgeon, with more than 30(thirty) years of clinical experience, as well as being Board Certified in Osteopathic Manipulative Medicine and Certified by the American Academy of Pain Management. I have also been studying in these areas of pain and disease management using crystal devices for over eight(8) years since 1997, and have spoken and taught internationally in these areas on numcrous occasions and conducted workshops that have taught more than three hundred fifty(350) therapists the treatment processes in these areas.

Part of my prior knowledge of devices in these areas is also described on pages 1 and 2 of the background section of subject application specification. As detailed in the background section, I previously developed a basic device entitled: "Tens Cam" which only used a single fixed frequency generating crystal that solely relied on an electromagnetic induction coil to drive the single crystal. A fixed frequency of approximately 8 Hertz was generated by an electromagnetic source in a narrow beam having a diameter of approximately 1 to approximately 2 millimeters. The delay time for therapeutic effects of the Basic Tens Cam unit was approximately two to approximately four(4) minutes to generate therapeutic effects on the patient which became difficult to do over continuous treatments that required the operator to physically hold the unit which weighed almost one pound, above the patient being treated. In addition other problems existed with this unit. Operator fatigue was an inherent result of using this unit. The various versions of the Tens Cam are described below and in the appendix.

The Basic Tens Cam unit required an operator to physically hold the unit above a patient throughout the treatment process so that the operator received direct vibratory effects from physically holding the unit. The combination of constantly holding the weight of the unit and the direct vibratory effects, along with the operator being constantly within the generation field of the unit created side effects such as but not limited to fatigue and malaise and Carpal Tunnel Syndrome. Operators repeatedly using the Basic Tens Cam have complained of side effects of median nerve paraesthesia, which is a numbness and tingling effect to their hands and fingers.

Additional problems with the Basic Tens Cam unit as with other electromagnetic and with vibratory units is that all these units are known to give off heat which has caused tissue damage. Furthermore, Basic Tens Cam and other prior art type units have limitations as to the tissue penetration being achieved, since the tissue penetration depth is limited by the mechanical nature of the vibrations.

Before we applied for the subject patent application it was not publicly known to modify the Basic Tens Cam with "amplifying and diffusing" components, such as using a "lens", "Crystal Sphere sphere" for generating an ouput beam having "a diameter of approximately 5cm to approximately 6cm", which is required in all our independent patent claims. In addition, none of the cited prior art references describe such features.

In addition, none of the cited references was able to use "additional energy to aid in the therapy treatment. Thus, these prior art devices are limited to mechanical devices and do not incorporate other approaches with their use. Furthermore, using strictly handheld supported devices can potentially injure the patients themselves, if the operator directly contacts the patients with the devices.

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It was NOT until the subject invention that I discovered that we can actually provide a "medical treatment device" and "method of treating effected body parts with a pulse emitting tool" referenced in the claims of a "main longitudinal crystal; side crystals arranged about side portions of the main longitudinal crystal...the side crystals being perpendicular to a "longitudinal axes of the main longitudinal crystal, the side crystals being used as antennae to receive ambient energy fields about the device; means for generating a resonating frequency in the main crystal which is focused by the emitting tip portion...toward an effected body part for treatment for up to approximately 2(two) minutes....(with) means for forming a beam from the emitting tip portion having a diameter of approximately 5cm to approximately 6cm", claim 1, the combined steps of "providing a main longitudinal crystal...positioning side crystals ...perpendicular to the longitudinal axes of the main longitudinal crystal; picking up ambient energy fields surrounding the tool through the side crystals....emitting pulses having a selected resonating frequency ...toward a body part for treatment... amplifying and diffusing the pulses being emitted from the main body by a lens positioned adjacent to the emitting endrunning the pulse emitting tool up to approximately 2 minutes....", claim 17, and the combination of " medical treatment device comprising: a main longitudinal solid crystal....a crystal sphere next to the emitting tip portion of the main longitudinal body....power source for generating a resonating frequency in the main crystal through the emitting tip portion of the main longitudinal crystal into an output signal which is amplified and diffused by the crystal sphere toward an effected body part for treatment for up to approximately 2(two) minutes; and side crystals being perpendicular to a longitudinal axes of the main longitudinal crystal, the side crystals being used as antennae to receive ambient energy fields about the device, claim 28.

Attached is an Appendix that details the general development and public disclosure dates of the various versions of the Tens Cam Device, and the subject Pulse Cam Invention. The background section of the subject application describes and refers solely to the Basic Tens Cam and the Tens Cam Model 100. Basically, the Basic Tens Cam and the Model 100 version were a single longitudinal crystal with a coil wrap. It was not until Model 102, which was not publicly disclosed until March 2002, after we filed the subject patent application, where we discovered that adding the Crystal Sphere Lens created additional novel results of amplifying and diffusing the output beam to a diameter of approximately 5cm to approximately 6cm. The novel "perpendicular" side mounted "crystals" to date have not been publicly disclosed.

The public disclosure dates of the Tens Cam devices with their main components are summarized below:

TENS CAM MODELS

BASIC & Model 100-Crystal With Coil Wrap-First Public Disclosure March 25, 1999

Model 102-Sphere Lens with Coil Wrapped Crystal-First Public Disclosure March 22, 2002

Model 103-LED in front of Model 102-First Public Disclosure October 12, 2003

**Current Model-PULSE CAM-Subject of Current Patent Application
Combines Model 102 with perpendicular side mounted crystals**

The use of the "amplifying and diffusing" components, "lens", "Crystal Sphere" for generating an output beam having "a diameter of approximately 5cm to approximately 6cm", was first publicly disclosed in Model 102 in March 2002 which was AFTER my patent application was filed in February 27, 2002. Additionally, the side mounted crystals in the subject application have NOT been publicly disclosed.

Thus, there was NO public disclosure of our claimed use of "amplifying and diffusing" components", "lens", "Crystal Sphere" for generating an output beam having "a diameter of

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approximately 5cm to approximately 6cm", that was more than one year before the February 27, 2002 filing of the subject patent application.

4. Since I developed the Tens Cam devices, I am very familiar with the Primary Reference: TENS CAM DEVICE which was cited in the office action dated October 26, 2005.

As described above and as shown in the attached appendix, the Basic Tens Cam device and Tens Cam Model 100 was limited to a single crystal with a coil wrap that must run for approximately 2 minutes to 4 minutes. There was NO "amplifying and diffusing" components, "lens", "Crystal Sphere sphere" for generating an output beam having "a diameter of approximately 5cm to approximately 6cm", or similar component(s) used in the Basic Tens Cam or in the Tens Cam Model 100.

The Basic Tens Cam device and Tens Cam Model 100 that was publicly disclosed more than one year before the subject invention filing date is structurally and functionally different than the subject invention, and the Basic Tens Cam device and Tens Cam Model 100 have components and operating features substantially different than the subject invention.

For example, subject claims 1, 17 and 28 require "amplifying and diffusing" components("lens", "Crystal Sphere" for generating an output beam having "a diameter of approximately 5cm to approximately 6cm"), along with "side crystals" oriented "perpendicular" to the "main crystal" and therapy occurs up to approximately 2 minutes in time. Clearly, the Basic Tens Cam device and Tens Cam Model 100 cannot anticipate our invention or render our invention to be obvious.

I am also familiar with the U.S. Patent 1,510,080 to Murphy, which was applied for in 1922, which is well before the use of "crystals" that are used and claimed in the subject invention. Murphy clearly requires the use of a heat generating "radiator 23" that he only describes as a "incandescent electric lamp or other device for emitting rays and is of the usual construction.", page 1, lines 87-89. Murphy is clearly concerned with the generation of heat from the "radiator" since, he mentions on page 1, lines 18-23 that he requires an "effective means for the ventilation of the enclosure..to eliminate(other components) from becoming broken by the effect of heat from the radiator." Murphy requires the use of "top and bottom ...ventilating outlet 9 and 10 respectively.." page 1, lines 54-56 and "ventilating space 17", page 1, lines 66-68, "ventilating opening 20...similar opening 21...passage-ways 22, page 1, lines 76-85 to dissipate this heat.

Clearly, Murphy has the same heat generating problems that we described in the background section of our patent application. As such, Murphy is no better than the known prior art devices that we referenced in the background section of the invention. Murphy would not be practical or useful for the treatments that my device performs.

Additionally, Murphy requires an elaborate setup and combination of additional components such as "annular flange 13", "channel bar 14", "pair of mirrors 16", "two glass strips 18", "prisms 24", "auxiliary reflector 26", "glass strips 28", "filter plates 7 and 8", in addition to the radiating heat source 23. Murphy clearly requires the use of heat for medical therapy. Again, the subject invention does not use any heat for medical therapy.

Also, Murphy has no "amplifying and diffusing" components("lens", "Crystal Sphere" for generating an output beam having "a diameter of approximately 5cm to approximately 6cm"), that are required by the patent application independent claims 1, 17 and 28. Murphy instead requires "filter plates 7 and 8", page 2, that he states modifies the "color" of his output which has nothing to do with "amplifying and diffusing" components("lens", "Crystal Sphere" for generating an output beam having "a diameter of approximately 5cm to approximately 6cm"), that are required by our claims.

Again, this complex and elaborate setup of components within a large cumbersome drum holder with conical end used in Murphy is no better than the prior art devices I referenced in the background section of our patent application. As such Murphy would not be practical or useful for the treatments that my invention performs.

Nowhere does Murphy describe, teach, or suggest a "medical treatment device" and "method of treating effected body parts with a pulse emitting tool" referenced in the claims of a "main longitudinal

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crystal; side crystals arranged about side portions of the main longitudinal crystal...the side crystals being perpendicular to a "longitudinal axes of the main longitudinal crystal, the side crystals being used as antennae to receive ambient energy fields about the device; means for generating a resonating frequency in the main crystal which is focused by the emitting tip portion...toward an effected body part for treatment for up to approximately 2(two) minutes....(with) means for forming a beam from the emitting tip portion having a diameter of approximately 5cm to approximately 6cm", claim 1, the combined steps of "providing a main longitudinal crystal....positioning side crystals ...perpendicular to the longitudinal axes of the main longitudinal crystal; picking up ambient energy fields surrounding the tool through the side crystals...emitting pulses having a selected resonating frequency ...toward a body part for treatment... amplifying and diffusing the pulses being emitted from the main body by a lens positioned adjacent to the emitting endrunning the pulse emitting tool up to approximately 2 minutes....", claim 17, and the combination of " medical treatment device comprising: a main longitudinal solid crystal....a crystal sphere next to the emitting tip portion of the main longitudinal body....power source for generating a resonating frequency in the main crystal through the emitting tip portion of the main longitudinal crystal into an output signal which is amplified and diffused by the crystal sphcre toward an effected body part for treatment for up to approximately 2(two) minutes; and side crystals being perpendicular to a longitudinal axes of the main longitudinal crystal, the side crystals being used as antennae to receive ambient energy fields about the device, claim 28.

Thus, the novel combinations in independent claims 1, 17 and 28, are clearly outside the scope of the 1922 filed patent to Murphy.

5. As described in our patent application on page 9 we have test data that shows treatment has been effective with various physically painful ailment areas such as those listed in Table 1(which is reprinted below) within time frames of up to approximately 2 minutes which is substantially less than the approximately 2 to approximately 4 minutes that was needed with the prior art Basic Tens Cam unit and Tens Cam Model 100. Ultrasound studies and scans taken from various patients that have been treated by the subject invention have shown that less inflammation exists in the body areas where these painful ailments occur. Clearly, I have documented that our invention reduces the inflammation and pain in the body structures which is the bases of its pain relief.

TABLE 1.

AILMENTS Column 1 List

- Ankle Sprain
- Tennis Elbow
- Torn Meniscus
- Back Pain
- Nerve Root
- Bursitis
- Neck Pain
- Macular Degeneration
- Hernia
- Gallbladder
- Foot Pain
- Scars

AILMENTS Column 2 List

- Headache
- Earache
- Sinusitis
- Burns
- Wounds
- Abrasions
- GERD
- TMJ
- Morton's Neuroma
- Arthritis
- Sore Throat
- Shingles

6. I have tested the Basic TENS CAM device and TENS CAM Model 100 and found that these devices would not provide the therapy test results that were achieved with our invention.

I have also tested heat generating devices such as the one described in the Murphy patent and other devices similar to those cited by the Patent Office. These devices would also not provide the therapy test results that were achieved with my invention.

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In my opinion the Basic TENS CAM device, TENS CAM Model 100 and the patents in individually or in combination referenced by the Patent Office would not be able to achieve the novel results that were achieved by the novel combination of "medical treatment device" and "method of treating effected body parts with a pulse emitting tool" referenced in the claims of a "main longitudinal crystal; side crystals arranged about side portions of the main longitudinal crystal...the side crystals being perpendicular to a "longitudinal axes of the main longitudinal crystal, the side crystals being used as antennae to receive ambient energy fields about the device; means for generating a resonating frequency in the main crystal which is focused by the emitting tip portion...toward an effected body part for treatment for up to approximately 2(two) minutes....(with) means for forming a beam from the emitting tip portion having a diameter of approximately 5cm to approximately 6cm", claim 1, the combined steps of "providing a main longitudinal crystal....positioning side crystals ...perpendicular to the longitudinal axes of the main longitudinal crystal; picking up ambient energy fields surrounding the tool through the side crystals....emitting pulses having a selected resonating frequency ...toward a body part for treatment... amplifying and diffusing the pulses being emitted from the main body by a lens positioned adjacent to the emitting endrunning the pulse emitting tool up to approximately 2 minutes....", claim 17, and the combination of " medical treatment device comprising: a main longitudinal solid crystal....a crystal sphere next to the emitting tip portion of the main longitudinal body....power source for generating a resonating frequency in the main crystal through the emitting tip portion of the main longitudinal crystal into an output signal which is amplified and diffused by the crystal sphere toward an effected body part for treatment for up to approximately 2(two) minutes; and side crystals being perpendicular to a longitudinal axes of the main longitudinal crystal, the side crystals being used as antennae to receive ambient energy fields about the device, claim 28.

7. In the prior art cited there was no understanding or any discussions to the novel combination of a "medical treatment device" and "method of treating effected body parts with a pulse emitting tool" referenced in the claims of a "main longitudinal crystal; side crystals arranged about side portions of the main longitudinal crystal...the side crystals being perpendicular to a "longitudinal axes of the main longitudinal crystal, the side crystals being used as antennae to receive ambient energy fields about the device; means for generating a resonating frequency in the main crystal which is focused by the emitting tip portion...toward an effected body part for treatment for up to approximately 2(two) minutes....(with) means for forming a beam from the emitting tip portion having a diameter of approximately 5cm to approximately 6cm", claim 1, the combined steps of "providing a main longitudinal crystal....positioning side crystals ...perpendicular to the longitudinal axes of the main longitudinal crystal; picking up ambient energy fields surrounding the tool through the side crystals....emitting pulses having a selected resonating frequency ...toward a body part for treatment... amplifying and diffusing the pulses being emitted from the main body by a lens positioned adjacent to the emitting endrunning the pulse emitting tool up to approximately 2 minutes....", claim 17, and the combination of " medical treatment device comprising: a main longitudinal solid crystal....a crystal sphere next to the emitting tip portion of the main longitudinal body....power source for generating a resonating frequency in the main crystal through the emitting tip portion of the main longitudinal crystal into an output signal which is amplified and diffused by the crystal sphere toward an effected body part for treatment for up to approximately 2(two) minutes; and side crystals being perpendicular to a longitudinal axes of the main longitudinal crystal, the side crystals being used as antennae to receive ambient energy fields about the device, claim 28.

8. Based on my opinion and vast research experience in these areas it would not have been anticipated or obvious to a person of ordinary skill in the art to invent the novel combination of a "medical treatment device" and "method of treating effected body parts with a pulse emitting tool" referenced in the claims of a "main longitudinal crystal; side crystals arranged about side portions of the main longitudinal crystal...the side crystals being perpendicular to a "longitudinal axes of the main longitudinal crystal, the side crystals being used as antennae to receive ambient energy fields about the device; means for generating a resonating frequency in the main crystal which is focused by the emitting

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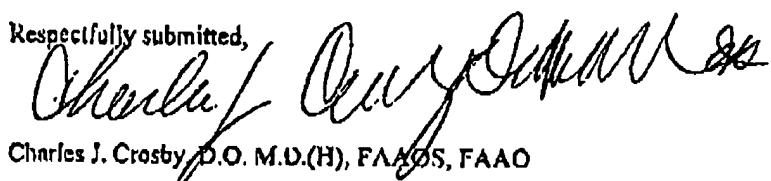
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tip portion...toward an effected body part for treatment for up to approximately 2(two) minutes....(with) means for forming a beam from the emitting tip portion having a diameter of approximately 5cm to approximately 6cm", claim 1, the combined steps of "providing a main longitudinal crystal...positioning side crystals...perpendicular to the longitudinal axes of the main longitudinal crystal; picking up ambient energy fields surrounding the tool through the side crystals...emitting pulses having a selected resonating frequency...toward a body part for treatment...amplifying and diffusing the pulses being emitted from the main body by a lens positioned adjacent to the emitting end...running the pulse emitting tool up to approximately 2 minutes....", claim 17, and the combination of "medical treatment device comprising: a main longitudinal solid crystal...a crystal sphere next to the emitting tip portion of the main longitudinal body...power source for generating a resonating frequency in the main crystal through the emitting tip portion of the main longitudinal crystal into an output signal which is amplified and diffused by the crystal sphere toward an effected body part for treatment for up to approximately 2(two) minutes; and side crystals...being perpendicular to a longitudinal axes of the main longitudinal crystal, the side crystals being used as antenna to receive ambient energy fields about the device, claim 28.

9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,



Charles J. Crosby, D.O. M.D.(H), FAAOS, FAAO

Dated: October 28, 2005

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